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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/163,713    09/30/98    LUSTIG

K    T97-012-1

EXAMINER

HM12/0117

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PAK, M

ART UNIT

PAPER NUMBER

1646

DATE MAILED:

01/17/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

09/163,713

Applicant(s)

Lustig et al.

Examiner

Michael Pak

Group Art Unit

1646

☒ Responsive to communication(s) filed on Nov 14, 2000

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 32-61 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 32-61 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

*Response to Amendment*

1. The amendment filed 14 November 2000 (Paper No. 10) has been entered.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Applicant's arguments filed 14 November 2000 (Paper No. 10) have been fully considered but they are not found persuasive.

*Claim Rejections - 35 USC § 112, 1st paragraph*

4. Claims 32-53 and 56-61 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Written description rejection.

Claims 32-53 and 56-61 encompass a peptide comprising L1-L3 which are any hydrophobic amino acids. However, the specification only discloses species which have L1-L3 comprising leucine as the amino acid and do not disclose the genus of other amino acids which are hydrophobic. *University of California v.*

*Eli Lilly and Co. (CAFC) 43 USPQ2d 1398* held that a generic claim to human or mammalian when only the rat protein sequence was disclosed did not have written description in the specification. Thus, the only disclosure to leucine in L1-L3 does not have written description for the genus of hydrophobic amino acid sequences.

5. Claims 32-61 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a peptide sensor consisting of a peptide comprising LXXLL where the L is a leucine, does not reasonably provide enablement for a peptide sensor consisting of a peptide comprising LXXLL where the L is a hydrophobic amino acid or a peptide sensor consisting of a peptide comprising SEQ ID NO:11. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claims 54-55 are drawn to a peptide comprising SEQ ID NO:11 which does not work as disclosed in the specification on page 6 in Table 2. It would require undue experimentation to use a peptide consisting of SEQ ID NO:11 in the claimed method because Table 2 teaches that SEQ ID NO:11 does not work in the method.

Claims 32-53 and 56-61 encompass a peptide comprising L1-L3 as any hydrophobic amino acid. However, the specification does

not teach using any hydrophobic amino acid for L1-L3. The specification teaches using L1-L3 with leucine but not with any hydrophobic amino acid. It is known in the art that leucine amino acids play a special role in protein-protein interaction. However, it would require empirical experimentation to determine whether hydrophobic amino acids would have the same protein-protein interaction as in the co-activator and nuclear receptor interaction. It would require undue experimentation for one of skill in the art to determine whether hydrophobic amino acids could be used to replace leucine.

*Claim Rejections - 35 USC § 112, 2nd paragraph*

6. Claims 32-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 32-34 are confusing because claim 32 measuring step detects the sensor yet in the dependent claim 33 the measuring step detects the first receptor. Furthermore, claim 33 does not appear to further limit claim 32.

7. No claims are allowed.

8. Applicant's amendment necessitated the new ground(s) of

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Art Unit: 1646

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rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See M.E.P.. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Pak, whose telephone number is (703) 305-7038. The examiner can normally be reached on Monday through Friday from 8:30 AM to 2:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

*Michael D. Pak*  
Michael Pak  
Primary Patent Examiner  
Art Unit 1646  
12 January 2001